

FEB - 9 1998



4445-310 S.W. 35th Terrace  
Gainesville, Florida 32608  
TEL: 352/338-0440 FAX: 352/338-0662

K980191

P1071

**510(k) SUMMARY**

**APPLICANT:** Medical Device Technologies, Inc.  
4445-310 SW 35th Terrace  
Gainesville, FL 32608

**CONTACT:** Karl Swartz  
Quality Assurance Manager

**TELEPHONE:** (352)338-0440  
fax (352)338-0662

**TRADE NAMES:** Manan™ Biliary Drainage Catheter

**COMMON NAME:** Biliary drainage catheter

**CLASSIFICATION NAME:** §876.5010-Biliary Catheter and Accessories

**SUBSTANTIAL EQUIVALENCE:**

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Manan Medical Products	Biliary Drainage Catheter	K954043

**DESCRIPTION OF DEVICE:**

Manan drainage catheters are made from a biocompatible implantable urethane (Tecoflex) that has been used extensively in both short and long term implantable medical devices. This material softens at body temperature thus minimizing tissue trauma. The catheters come in various end configurations: Locking pigtail loop and non-locking pigtail. Also included with the catheters are flexible stiffening cannula. Non-flexible cannula and luer septum caps are optional items.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Karl Swartz  
Quality Manager  
Medical Device Technologies, Inc.  
4445-310 S.W. 35<sup>th</sup> Terrace  
Gainesville, FL 32608

Re: K980191  
Manan™ Biliary Drainage Catheter  
Dated: December 29, 1997  
Received: January 20, 1998  
Regulatory Class: II  
21 CFR 876.5010/Procode: 78 FGE

Dear Mr. Swartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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510(k) Number (if known): K97

Device Name: Manan™ Biliary Drainage Catheter

Indications for Use:

The Manan™ Biliary Drainage Catheter is for percutaneous biliary drainage.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Roder R. Rathling  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K980191

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)



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